

BEST AVAILABLE COPY

PATENT COOPERATION TREATY

PCT

10/009709

REC'D 27 SEP 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

PCT

(PCT Article 36 and Rule 70)

| | | |
|---|---|--|
| Applicant's or agent's file reference NST-0005-PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/SE00/00930 | International filing date (day/month/year) 11.05.2000 | Priority date (day/month/year) 17.05.1999 |
| International Patent Classification (IPC) or national classification and IPC: C07K 7/06, A61K 38/08, A61P 1/02 | | |
| Applicant Strömberg, Nicklas et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|---|--|
| Date of submission of the demand 12.12.2000 | Date of completion of this report 17.09.2001 |
| Name and mailing address of the IPEA/SE PCT/SE00/00930 P-1 1 11 STOCKHOLM Facsimile No. 08-667 72 88 | Authorized officer Carolina Gómez Lagerlöf/BS Telephone No. 08-782 25 00 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EE00/00930

1. Basis of the report

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/00930

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 5

because:

☒ the said international application, or the said claims Nos. 5

relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

PCT/SE00/00930

1. Statement

| | | | |
|-------------------------------|--------|-----------------|-----|
| Novelty (N) | Claims | <u>2-4, 7</u> | YES |
| | Claims | <u>1, 6, 8</u> | NO |
| Inventive step (IS) | Claims | <u></u> | YES |
| | Claims | <u>1-4, 6-8</u> | NO |
| Industrial applicability (IA) | Claims | <u>1-4, 6-8</u> | YES |
| | Claims | <u></u> | NO |

The claims disclose oligopeptides containing two arginine residues and a composition containing them. The claims further disclose the manufacture of a medicament for prevention of dental caries containing the oligopeptides.

A. WO 9914231, A2
B. WO9407523, A1, see claim 1 seq 6.
C. US 4225579
D. J. Immunol., 1994, 152 (7), pp 3645-3653

Document A discloses peptides that are covered by the scope of claim 1. These peptides can be used in the treatment of caries (see claim 9).

Document B relates to antimicrobial peptides that also is covered by the scope of claim 1. These peptides are used in the treatment of gingivitis or periodontitis.

Document C shows peptides having 2-4 amino acid units where at least one is arginine. These peptides are effective to combat caries. Compositions containing these peptides can be used in chewing gum, dental care products etc.

Document D discloses the peptide APPRGR that is one of the preferred claimed peptides. However, the document does not show that the peptide has a medical use. Document D shows the general state of the art.

.../...

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V

Peptides according to claim 1 are known. Compositions containing these peptides are also known.

Since it is known that short peptides containing to arginine can be used in the treatment of caries, it is considered obvious to a person skilled in the art to use other short peptides containing arginine for the treatment of caries.

Thus, claims 1, 6 and 8 are not considered to fulfil the requirements of novelty and inventive step.

Claims 2-4 and 7 are considered to fulfil the requirement of novelty but not that of inventive step.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/00930

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: C07K 7/06, A61K 38/08, A61P 1/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE, DK, FI, NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--|-----------------------|
| X | US 4225579 A (ISRAEL KLEINBERG), 30 Sept 1980 (30.09.80) | 1-8 |
| X | WO 9914231 A2 (FORSSMANN, WOLF-GEORG), 25 March 1999 (25.03.99) | 1-8 |
| X | WO 9407523 A1 (EMORY UNIVERSITY ET AL), 14 April 1994 (14.04.94) | 1-8 |
| A | Journal of Immunology, Volume 152, 1994, Yasuo Yamauchi et al, "Recombinant and Native Zymogen Forms of Human Complement Factor D1" page 3645 - page 3652 | 4 |

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

Special categories of cited documents

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (no specification)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

Date of the actual completion of the international search

19 Sept 2000

Date of mailing of the international search report

29-09-2000

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer

Carolina Gómez Lagerlöf/GH
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/SE 00/00930

| Patent document cited in search report | | | Publication date | Patent family member(s) | | Publication date |
|---|---------|----|---------------------|----------------------------|------------|---------------------|
| US | 4225579 | A | 30/09/80 | NONE | | |
| ----- | | | | | | |
| WO | 9914231 | A2 | 25/03/99 | DE | 19805385 C | 12/08/99 |
| ----- | | | | | | |
| WO | 9407523 | A1 | 14/04/94 | CA | 2145313 A | 14/04/94 |
| | | | | EP | 0685754 A | 09/08/95 |
| | | | | JP | 8502262 T | 12/03/96 |
| | | | | US | 5447914 A | 05/09/95 |
| | | | | US | 5798336 A | 25/08/98 |
| ----- | | | | | | |

INTERNATIONAL SEARCH REPORT

Search request No.
PCT/SE00/00930

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international-type search report has not been established in respect of certain claims for the following reasons:

1. ☒ Claims No.: 5
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 5 relates to a method of treatment of the human or animal body by surgery or by therapy/a diagnostic method practised on the human or animal body/ Rule. 39.1.(iv). Nevertheless, a search has been executed for this claim. The search has been based on the alleged effects of the compound/composition.
2. ☐ Claims No.:
because they relate to parts of the national application that do not comply with the prescribed requirements to such an extent that no meaningful international-type search can be carried out, specifically:

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international-type search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international-type search report covers only those claims for which fees were paid, specifically claims No.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international-type search report is restricted to the invention first mentioned in the claims, it is covered by claims No.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

PCT

INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|--|--|---|
| (51) International Patent Classification ⁷ : C07K 7/06, A61K 38/08, A61P 1/02 | A1 | (11) International Publication Number: WO 00/69890 (43) International Publication Date: 23 November 2000 (23.11.00) |
| (21) International Application Number: PCT/SE00/00930 (22) International Filing Date: 11 May 2000 (11.05.00) (30) Priority Data: 9901773-3 17 May 1999 (17.05.99) SE (71)(72) Applicants and Inventors: STRÖMBERG, Nicklas [SE/SE]; Rågängen 6A, S-903 37 Umeå (SE). JOHANSSON, Ingegerd [SE/SE]; Svampvägen 18, S-903 39 Umeå (SE). (74) Agent: CONIMAR AB; Box 2086, S-141 02 Huddinge (SE). | (81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> | |
| (54) Title: PREVENTION OF DENTAL CARIES (57) Abstract A penta- to decapeptide containing two or more Arg protecting against dental caries is comprised by the amino acid sequence GlyGlyHisProArgProProArgGlyArgProGlnGlyProProGlnGln. Also disclosed is a composition for preventing dental caries comprising an effective amount of the peptide, and a corresponding method of use. | | |

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

| | |
|---|---|
| Date of mailing (day/month/year) 02 February 2001 (02.02.01) | |
| International application No. PCT/SE00/00930 | Applicant's or agent's file reference NST-0005-PCT |
| International filing date (day/month/year) 11 May 2000 (11.05.00) | Priority date (day/month/year) 17 May 1999 (17.05.99) |
| Applicant STRÖMBERG, Nicklas et al | |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 12 December 2000 (12.12.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|---|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35 | Authorized officer A. Karkachi Telephone No.: (41-22) 338.83.38 |
|---|---|

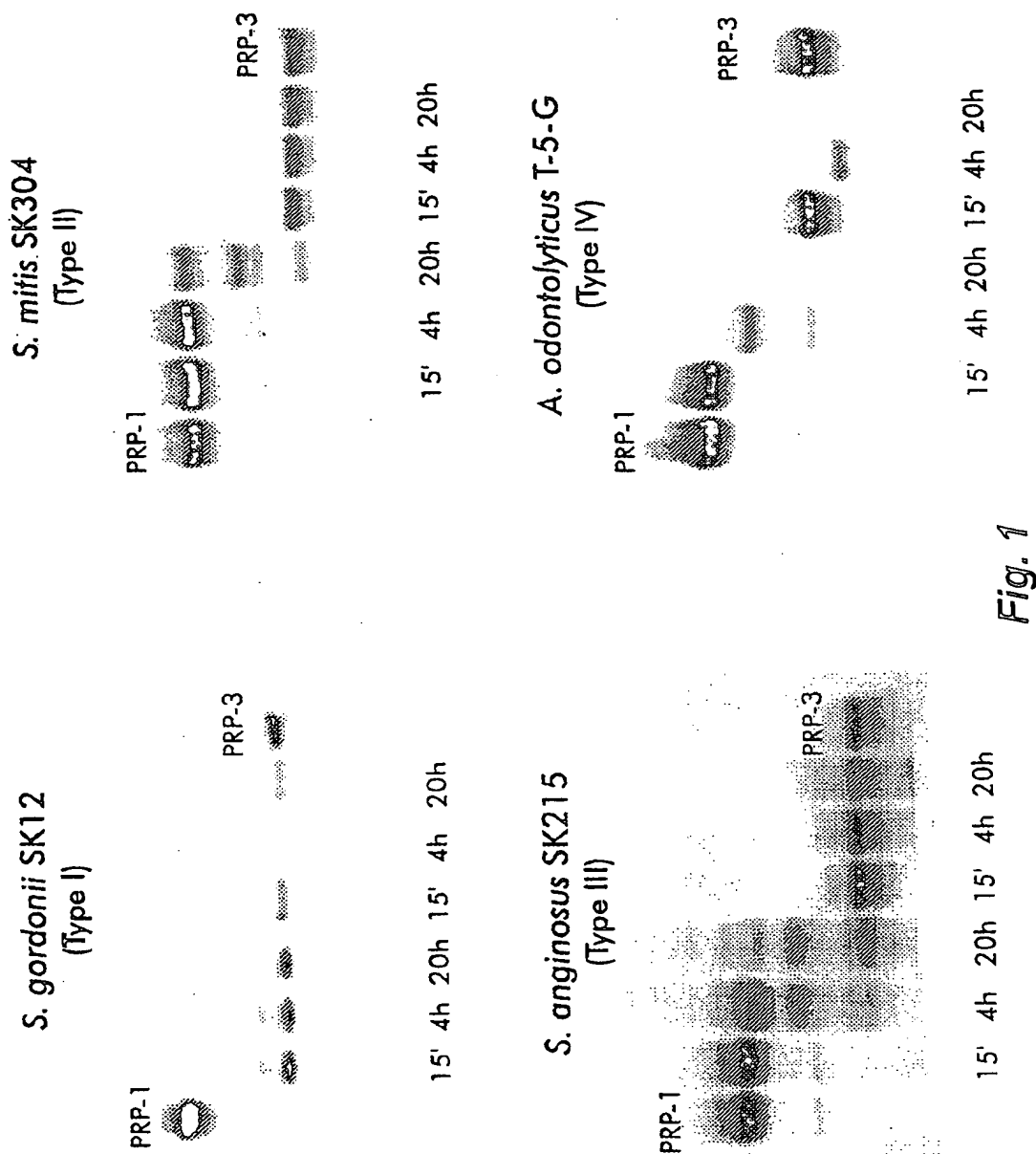


Fig. 1

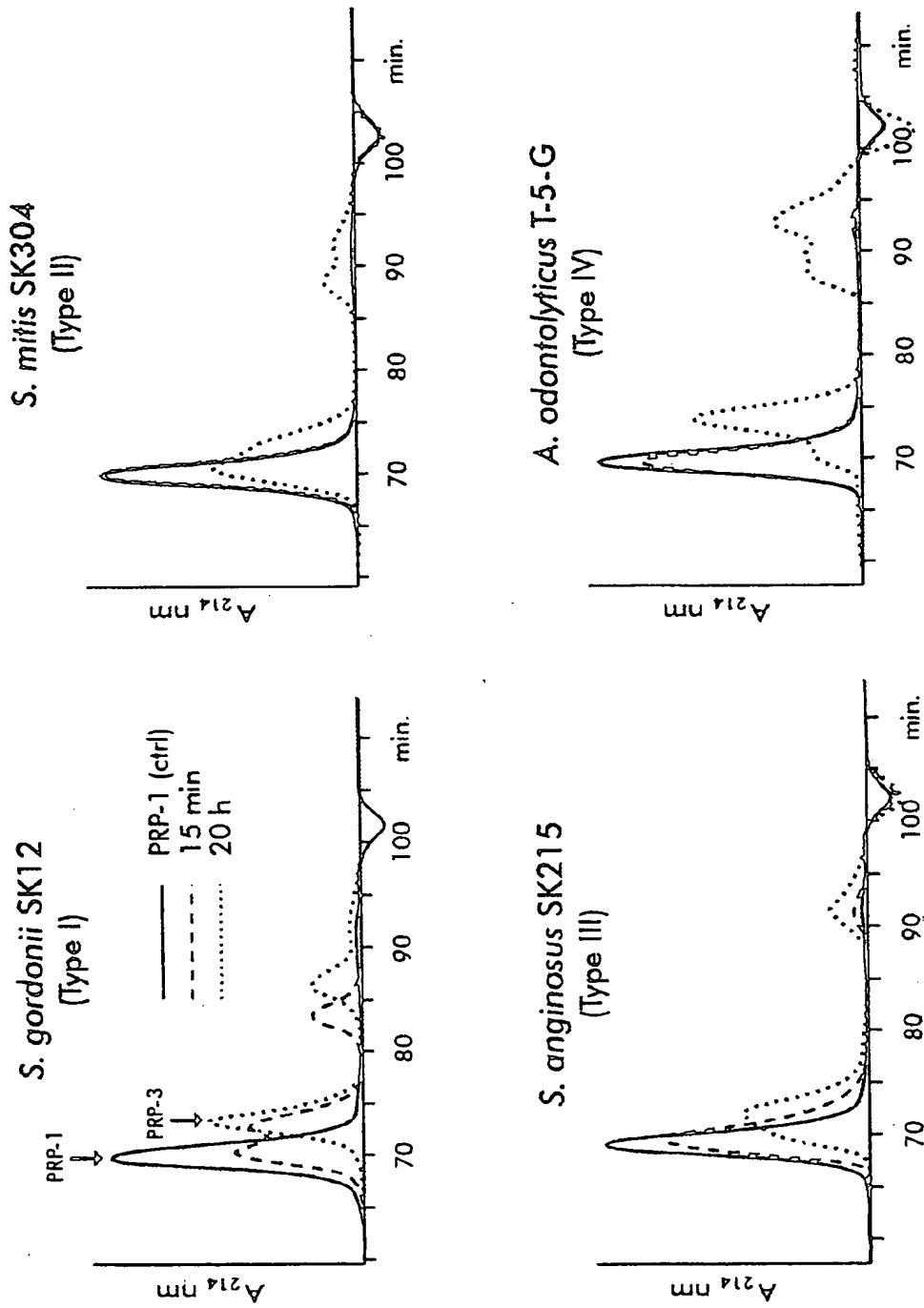


Fig. 2

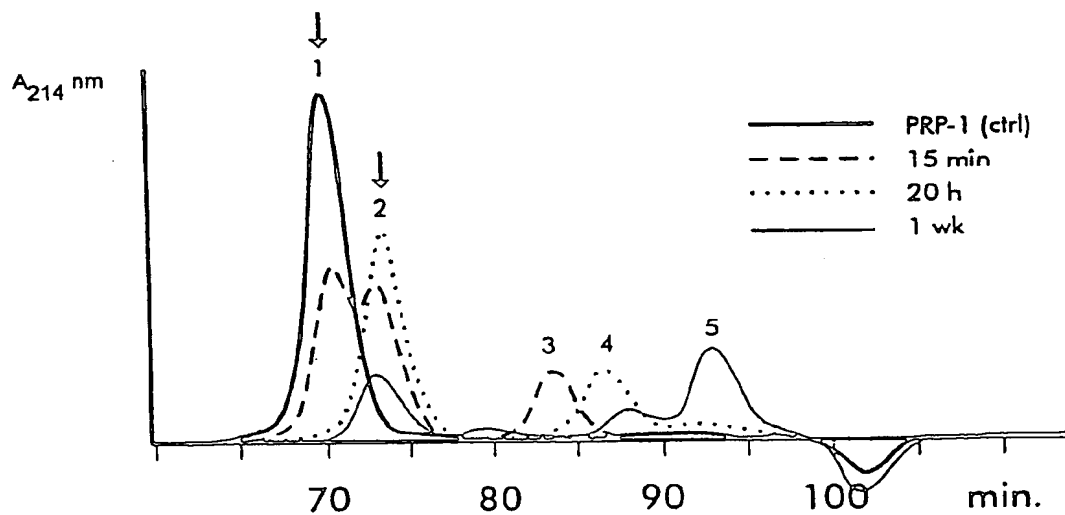


Fig. 3a

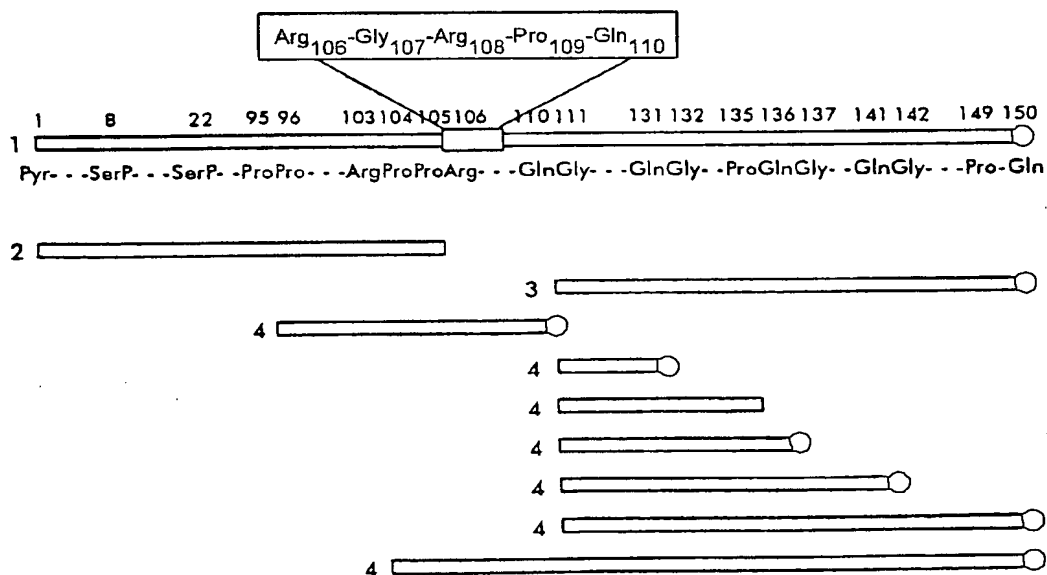


Fig. 3b